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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,173	08/06/2003	Robert Kain	ILLINC.026C1	3813

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,173	KAIN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 27-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 27-59 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 March 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-42 are indefinite in Claim 27, line 8 for the recitation "each of said microspheres" because the recitation lacks proper antecedent basis in the "first population of microspheres" and "second population of microspheres" of the claim. Therefore it is unclear whether the "each" refers to one of the populations, both of the populations and/or each microsphere in each of the populations. It is suggested the claim be amended to clarify e.g. "each microsphere of said first population of microspheres".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 27-28, 38, 43 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Drmanac et al (EP 0392546, published 17 October 1990).

Regarding Claim 27, Drmanac et al disclose a composition comprising a substrate, a first and second assay location (HA, hybridization area) each comprising a population of microsphere (DP, discrete particles) wherein each microsphere comprises a bioactive agent (i.e. DNA) and wherein the assay locations are separated from each other by a physical partition (i.e. well, page 7, left column, lines 22-58).

Regarding Claim 28, Drmanac et al discloses the composition wherein the microspheres are randomly distributed (page 7, left column, lines 22-58).

Regarding Claim 38, Drmanac et al discloses the composition wherein the bioactive agent is DNA (page 7, left column, lines 22-58).

Regarding Claim 43, Drmanac et al disclose a method of making a composition comprising a substrate a first and second assay location each location comprises a plurality of sites configured to hold a microsphere (HA, hybridization area) each comprising a population of microsphere (DP, discrete particles) wherein each microsphere comprises a bioactive agent (i.e. DNA) and wherein the assay locations are separated from each other by a physical partition (i.e. well, page 7, left column, lines 22-58).

Regarding Claim 53, Drmanac et al discloses the composition wherein the bioactive agent is DNA (page 7, left column, lines 22-58).

4. Claims 27-28, 31-32, 38, 43, 46, 47, 53, 58-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al (U.S. Patent No. 6,429,027, filed 24 February 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 27, Chee et al disclose a composition comprising a substrate, a first and second assay location each comprising a population of microsphere wherein each microsphere comprises a bioactive agent and wherein the assay locations are separated from each other by a physical partition (e.g. well, Column 6, lines 44-64 and Fig. 1.).

Regarding Claim 28, Chee et al disclose the composition wherein the microspheres are randomly distributed (e.g. Column 7, lines 66-67).

Regarding Claim 31, Chee et al disclose the composition wherein the partition is a ridge (as illustrated, Fig. 1A).

Regarding Claim 32, Chee et al disclose the composition wherein the partition is a trough)i.e. well as illustrated, Fig. 1A or tube, Column 7, lines 20-21).

Regarding Claim 38, Chee et al disclose the composition wherein the bioactive agent is DNA (Column 12, lines 16-33).

Regarding Claim 43, Chee et al disclose a method of making a composition comprising a substrate a first and second assay location each location comprises a plurality of sites configured to hold a microsphere wherein each microsphere comprises a bioactive agent and wherein the assay locations are separated from each other by a physical partition (e.g. well, Column 6, lines 44-64 and Fig. 1.).

Regarding Claim 46, Chee et al disclose the composition wherein the partition is a ridge (as illustrated, Fig. 1A).

Regarding Claim 47, Chee et al disclose the composition wherein the partition is a trough)i.e. well as illustrated, Fig. 1A or tube, Column 7, lines 20-21).

Regarding Claim 53, Chee et al disclose the composition wherein the bioactive agent is DNA (Column 12, lines 16-33).

Regarding Claim 58, Chee et al disclose the composition wherein the sites are formed by etching (Column 8, lines 19-22)

Regarding Claim 59, Chee et al disclose the composition wherein the sites are wells (Column 8, lines 16-22 and Fig. 1A).

5. Claims 27-28, 31-32, 38, 43, 46, 47, 53, 58-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al (U.S. Patent No. 6,998,274, filed 24 February 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 27, Chee et al disclose a composition comprising a substrate, a first and second assay location each comprising a population of microsphere wherein each microsphere comprises a bioactive agent and wherein the assay locations are separated from each other by a physical partition (e.g. well, Column 6, lines 44-64 and Fig. 1.).

Regarding Claim 28, Chee et al disclose the composition wherein the microspheres are randomly distributed (e.g. Column 7, lines 66-67).

Regarding Claim 31, Chee et al disclose the composition wherein the partition is a ridge (as illustrated, Fig. 1A).

Regarding Claim 32, Chee et al disclose the composition wherein the partition is a trough)i.e. well as illustrated, Fig. 1A or tube, Column 7, lines 20-21).

Regarding Claim 38, Chee et al disclose the composition wherein the bioactive agent is DNA (Column 12, lines 16-33).

Regarding Claim 43, Chee et al disclose a method of making a composition comprising a substrate a first and second assay location each location comprises a plurality of sites configured to hold a microsphere wherein each microsphere comprises a bioactive agent and wherein the assay locations are separated from each other by a physical partition (e.g. well, Column 6, lines 44-64 and Fig. 1.).

Regarding Claim 46, Chee et al disclose the composition wherein the partition is a ridge (as illustrated, Fig. 1A).

Regarding Claim 47, Chee et al disclose the composition wherein the partition is a trough)i.e. well as illustrated, Fig. 1A or tube, Column 7, lines 20-21).

Regarding Claim 53, Chee et al disclose the composition wherein the bioactive agent is DNA (Column 12, lines 16-33).

Regarding Claim 58, Chee et al disclose the composition wherein the sites are formed by etching (Column 8, lines 19-22)

Regarding Claim 59, Chee et al disclose the composition wherein the sites are wells (Column 8, lines 16-22 and Fig. 1A).

6. Claims 27-32, 38-47, 53-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Felder et al (U.S. Patent No. 6,232,066 filed 2 July 1998).

Regarding Claim 27, Felder et al disclose a composition comprising substrate comprising a surface having first and second assay locations wherein the assay location have discrete sites comprising microspheres with bioactive agents (wells or dimples, Column 6, lines 38-51) and wherein the locations are separated by a partition (i.e. physical barrier, Column 5, lines 19-28).

Regarding Claim 28, Felder et al disclose the composition wherein the microspheres are randomly distributed (Column 8, lines 39-42).

Regarding Claim 29, Felder et al disclose the composition wherein the partition is a non-permanent sealant (Column 5, lines 38-42).

Regarding Claim 30, Felder et al disclose the composition wherein the non-permanent sealant is silicon or wax (Column 5, line s38-42).

Regarding Claim 31, Felder et al disclose the composition wherein the partition is a ridge to prevent movement of reagents between assay locations (Column 5, lines 19-30).

Regarding Claim 32, Felder et al disclose the composition wherein the partition is a trough (e.g. "tubes or fluid-control channel" Column 5, lines 42-43).

Regarding Claim 38, Felder et al disclose the composition wherein the bioactive agent is DNA (Column 4, lines 34-62).

Regarding Claim 39, Felder et al disclose the composition wherein the substrate comprises a microscope slide (Column 5, line 2).

Regarding Claim 40, Felder et al disclose the composition wherein the substrate is with a hybridization chamber (i.e. the plate is covered for hybridization, Column 33, lines 49-52)

Regarding Claim 41, Felder et al disclose the composition wherein the substrate is a flexible membrane (i.e. nylon or nitrocellulose , Column 5, lines 3-4).

Regarding Claim 42, Felder et al disclose the composition wherein the first and second assay locations are separately enclosed (i.e. the partitioned regions are covered, Column 5, lines 19-45 and Column 33, lines 49-52).

Regarding Claim 43, Felder et al disclose method for making a composition comprising substrate comprising a surface having first and second assay locations wherein the assay location have discrete sites configured to hole a single microspheres having bioactive agents (subdivided regions within wells, Column 6, lines 38-51) wherein the microspheres are randomly distributed (Column 8, lines 39-42) and wherein the locations are separated by a partition (e.g. dimple or indentation, Column 5, lines 19-28 and Column 6, lines 38-42).

Regarding Claim 44, Felder et al disclose the method wherein the partition is a non-permanent sealant (Column 5, lines 38-42).

Regarding Claim 45, Felder et al disclose the method wherein the non-permanent sealant is silicon or wax (Column 5, line s38-42).

Regarding Claim 46, Felder et al disclose the method wherein the partition is a ridge to prevent movement of reagents between assay locations (e.g. dimple or indentation, Column 5, lines 19-28 and Column 6, lines 38-42).

Regarding Claim 47, Felder et al disclose the method wherein the partition is a trough (e.g. "tubes or fluid-control channel" Column 5, lines 42-43).

Regarding Claim 53, Felder et al disclose the method wherein the bioactive agent is DNA (Column 4, lines 34-62).

Regarding Claim 54, Felder et al disclose the method wherein the substrate comprises a microscope slide (Column 5, line 2).

Regarding Claim 55, Felder et al disclose the method wherein the substrate is with a hybridization chamber (i.e. the plate is covered for hybridization, Column 33, lines 49-52)

Regarding Claim 56, Felder et al disclose the method wherein the substrate is a flexible membrane (i.e. nylon or nitrocellulose , Column 5, lines 3-4).

Regarding Claim 57, Felder et al disclose the method wherein the first and second assay locations are separately enclosed (i.e. the partitioned regions preventing reagent flow between regions are covered, Column 5, lines 19-45 and Column 33, lines 49-52).

Regarding Claim 58, Felder et al disclose the method wherein the sites are formed by etching (Column 5, lines 28-30).

Regarding Claim 59, Felder et al disclose the method wherein the sites are wells (Column 5, lines 28-30).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 33-35 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et (U.S. Patent No. 6,232,066, filed 2 July 1998) in view of Lyman et al (U.S. Patent No. 6,555,361, filed 24 Marcy 1999).

Regarding Claims 33-35 and 48-50, Felder et al disclose a composition and method for making the composition comprising substrate comprising a surface having first and second assay locations wherein the assay location have discrete sites configured to hole a single microspheres having bioactive agents (subdivided regions within wells, Column 6, lines 38-51) wherein the microspheres are randomly distributed (Column 8, lines 39-42) and wherein the locations are separated by a partition (e.g. dimple or indentation, Column 5, lines 19-28 and Column 6, lines 38-42) wherein the partition is a non-permanent sealant (e.g. silicon or wax, Column 5, line s38-42).

Felder et al further teach the composition wherein the preferred partitions prevent reagent flow between the assay regions (Column 5, lines 23-25) but the reference is silent

regarding a gasket. However, hybridization chambers having a gasket adapted to fit within a indentation or channel of the chamber were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lyman et al.

Lyman et al teaches a hybridization composition comprising a sealant i.e. rubber gasket adapted to fit within an indentation on the substrate whereby the chamber is environmentally sealed to prevent ambient air or moisture from entering or escaping the chamber (Column 1, lines 62-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the rubber gasket of Lyman et al to the covered hybridization of Felder et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of preventing ambient air or moisture from entering or escaping the chamber to thereby provide the tightly controlled environment as desired in the art Lyman et al (Column 55-67).

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9. Claims 36-37 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et (U.S. Patent No. 6,232,066, filed 2 July 1998) in view of Fodor et al (U.S. Patent No. 6,310,189, filed 25 January 2000).

Regarding Claims 36-37 and 51-52 Felder et al disclose a composition and method for making the composition comprising substrate comprising a surface having first and second assay locations wherein the assay location have discrete sites configured to hole a single microspheres having bioactive agents (subdivided regions within wells, Column 6, lines 38-51) wherein the microspheres are randomly distributed (Column 8, lines 39-42) and wherein the locations are separated by a partition (e.g. dimple or indentation, Column 5, lines 19-28 and Column 6, lines 38-42).

Felder et al teach the wells are separated by a distance of 500 um (Column 6, line 35) and further teach the wells are subdivided to provide up to 900 "wells-within-wells" (Column 6, lines 43-47). Felder et al also teach a desire for increasing the number of spatially discrete regions i.e. allows for increasingly higher throughput (Column 5, lines 60-67). These teaching clearly suggest that the claimed less than 15 um spacing between assay locations was either know or clearly desired. Fodor et al teach a similar composition comprising microsphere-containing regions (Column 6, lines 23-30) wherein the regions have the claimed spacing i.e. 10um regions (Fig. 3 and Column 10, lines 17-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the region spacing known in the art to the substrate composition of Felder et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teach of Fodor et al and based on the desire in the art to provide for increasingly higher throughput (Felder et al, Column 5, lines 60-67).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 27-29, 36-44, 51-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-30 of U.S. Patent No. 6,429,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions comprising microsphere populations within assay locations. The claim sets merely differ in that the patent composition defines a number of microspheres per location. However, the open claim language "comprising" of the instant claims encompasses the additional elements of the patent composition.

12. Claims 27-29, 36-44, 51-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,998,274. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions comprising microsphere populations within assay locations. The claim sets merely differ in that the patent composition defines a number of microspheres per location. However, the open claim language "comprising" of the instant claims encompasses the additional elements of the patent composition.

13. Claims 27-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,770,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because sets of claims are drawn to very similar compositions comprising microsphere populations within assay locations. The claim sets merely differ in that the patent composition further

defines the substrate as a rigid support and molded layer. However, the open claim language "comprising" of the instant claims encompasses the additional elements of the patent composition.

14. Claims 27-29, 36-44 and 51-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-50 of copending Application No. 10/767,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because sets of claims are drawn to assay region comprising bioactive agents on a support. The claim sets merely differ in the arrangement of the limitations within the claims. For example, the instant independent claims are drawn to assay regions wherein the bioactive agents are on microspheres, while dependent claim 40 of the '476 claim set describes the microsphere embodiment. Therefore, the claim sets are drawn to inventions that are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 24, 2006